## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Masato FUJIOKA et al.

Title: THERAPEUTIC AGENTS FOR

> INNER EAR DISORDERS **CONTAINING AN IL-6**

ANTAGONIST AS AN ACTIVE

**INGREDIENT** 

Appl. No.: 10/593,776

International

3/24/2005

Filing Date:

371(c) Date: 9/22/06

Examiner: Prema Maria MERTZ

Art Unit: 1646

Confirmation 4182

Number:

## **DECLARATION**

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

I, Simon J. Elliott, declare:

Deposits under the terms of the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure have been made as follows:

The cell line which produces PM-1 antibody, deposited on July 12, 1989, with the 1. Fermentation Research Institute, Agency of Industrial Science and Technology, 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305 Japan, and accorded Accession No. FERM BP-2998. (The cell line was originally deposited on July 12, 1989, accorded Accession No. FERM P-10839, and was then transferred to Accession No. FERM BP-2998 on July 10, 1990.)

Atty. Dkt. No. 053466-0420

2. The hybridoma cell line which produces MR16-1 antibody, deposited on March 13,

1997, with the National Institute of Bioscience and Human Technology, Agency of Industrial

Science and Technology, 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305 Japan, and

accorded Accession No. FERM BP-5875.

3. The name and address of the depository institute has been changed to "the National

Institute of Advanced Industrial Science and Technology, Patent and Bio-Resource Center,

Chuo-6, 1-1, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305-5466, Japan."

4. Copies of the receipts of original deposits, and English translations, of the above-

identified international deposits are submitted herewith.

5. All restrictions on the availability to the public of the cultures deposited will be

irrevocably removed upon the granting of a patent from the above-identified application.

5. I hereby declare that all statements made herein of my own knowledge are true and

that all statements made on information and belief are believed to be true; and further that

these statements were made with the knowledge that willful false statements and the like so

made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the

United States Code and that such willful false statements may jeopardize the validity of the

application or any patent issued therefrom.

Respectfully submitted,

Date September 30, 2008

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Simon J. Elliott, Ph.D. Attorney for Applicant

Registration No. 54,083

DEPOSITOR

Name Tadamitsu Kishimoto

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

Address 5-31, Nakano-cho 3-chome,

Tondabayashi-shi,

Osaka 584

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the

(Deposition Number)

DEPOSITOR: PM1

FERM BP-2998

II. SCIENTIFIC DESCRIPTION AND/OR TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

a scientific description

x a proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under I above, which was received by it on July 12, 1989 (Date of the original deposit).

(Transferred from FERM P-10839 deposited on July 12, 1989.)

IV. INTERNATIONAL DEPOSITARY AUTHORITY

Fermentation Research Institute

Agency of Industrial Science and Technology

Director General

Tomoo Suzuki

1-3, Higashi 1 chome, Tsukuba-shi, Ibaraki-ken, 305, Japan

July 10, 1990

特許手続上の数生物の寄托の回線的承認 に関するブダベスト条約

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

BUDAPEST TREATY ON THE INTERNATIO-NAL RECOGNITION OF THE DEPOSIT OF MICROORCANISMS FOR THE PURPOSES OF

下記国際名託当局によって規則7.1に従い 発行される ・

原寄託についての受託証

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this

黔

氏名 (名称)

岸本 忠三

PATENT PROCEDURE

あて名

**6** 584 大阪府富田林市中野町 3丁目 5 春 3 1号

1. 境生物の表示	
(寄託者が付した疑別のための表示)	(受託委号)
PWI	以工研究等第 2998 号
	(FERM BP- 2998 ).
1. 科学的芸質及び分類学上の位置	
1 福の政主物には、次の享項を記載した文者が禿付されていた。	
□ 科学的世友	
. 分類学上の位置	
回、受頭及び受託・	
本国際存託当局は、平成 元年 7月12日(原務託日)に受領した「役の設定物を受託する。	
呼成 元年 7月12日に寄託された最工研發寄第 P- 10839 号より移動)	
TV. 田松菊託当局	
通商産業省工業技術院成生物工業技術研究所	
Fermina (Arence and Technology	
所義 鈴木智經濟品產品	
TOMOO (SUPULED) DIRECTOR CENERAL.	
. あて名: 日本白気設保つ(は市及1丁目1番3号(遊便符号305) 1-3. Higashi   chome Tsukubo-shi   baraki-ken 303. JAPAN	
平衣 2年(1990) 7月 10日	

特許手続上の微生物の寄託の国際的承認 に関するブタベスト条約

下記国際寄託当局によって規則7.1に従い 発行される。

原寄託についての受託証

BUDAPEST TREATY ON THE INTERNATIO-NAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

· issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this page.

殿

氏名(名称)

中外製薬株式会社

取締役社長 永山 治

寄託者

あて名 115 東京都北区評問5丁目5番1号

微生物の表示 (寄託者が付した識別のための表示) (受託番号) FERM BP- 5875 Rat-mouse hybridoma MR16-1 2. 科学的性質及び分類学上の位置 1 欄の微生物には、次の事項を記載した文書が添付されていた。 ■ 科学的性質 ■ 分類学上の位置 3. 受領及び受託 本国際委託当局は、 平成 9 年 3 月 1 3 日 (原寄託日) に受領した1 桐の微生物を受託する。

本国際寄託当局は、

4. 移管請求の受領

日 (原寄託日) に1 桐の微生物を受領した。

そして、

日 に原寄託よりブダベスト条約に基づく寄託への移管請求を受領した。

5. 国際寄託当局

通商産業省工業技術院生命工学工業技術研究所

National Institute of Bioscience and Human-Technology 名 称:

あて名: 日本 国 茨 核原 ② ( 即便番号305 ) 1-3, Higasb ( 即便番号305 )

305. JAPAN

平成 9年(1997) 3月13日

Depositor

Name: CHUGAI SEIYAKU

KABUSHIKI KAISHA

Representative: Osamu Nagayama

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

Address: 5-1, Ukima 5-chome,

Kita-ku, Tokyo 115

RECEIPT IN THE CASE OF AN ORIGINAL

DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY identified at the bottom of this

page.

IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the DEPOSITOR: Rat-mouse hybridoma MR16-1

(Deposition Number)

FERM BP-5875

SCIENTIFIC DESCRIPTION AND/OR TAXONOMIC DESIGNATION

The microorganism identified under 1 above was accompanied by:

- x a scientific description
- x a proposed taxonomic designation

(Mark with a cross where applicable)

3. RECEIPT AND ACCEPTANCE

This International Depositary Authority accepts the microorganism identified under 1 above, which was received by it on March 13, 1997 (Date of the original deposit)<sup>1</sup>.

4. RECEIPT OF TRANSFER

This International Depositary Authority accepted microorganism identified under 1 above, on \_\_\_\_\_\_\_\_\_(Date of the original deposit), and accepted a request for transfer to a deposition under Budapest treaty from the original deposition, on \_\_\_\_\_\_\_\_, (Transferred from FERM P \_\_\_\_\_\_\_\_ deposited on

5. INTERNATIONAL DEPOSITARY AUTHORITY

National Institute of Bioscience and Human-Technology

Agency of Industrial Science and Technology

Director General

Michio Oishi

1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken, 305, Japan

March 13, 1997